JAN 18 2008

SECTION 4

510(k) Summary of Safety and Effectiveness

Trade Name:	Cytophil Tissue Marker and Cytophil Tissue Market SM
Common Name:	Tissue Marker
Classification Name:	Marker, Radiographic, Implantable
Official Contact Name:	Greg Johnson President & CEO
Address:	Cytophil, Inc. 5546 N Santa Monica Blvd Whitefish Bay, WI 53217
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E-mail:	gjohnson@cytophil.com
Date Prepared:	8/8/2007

4.1 Intended Use

Cytophil Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

4.2 Product Description

Sterile, latex free, non-pyrogenic, semi-solid, cohesive subdermal implant. The principle durable component is synthetic calcium hydroxylapatite. The semi-sold nature is created by suspending the calcium hydroxylapatite particles in a durable high yield strength thixotropic gel. The isotonic gel carrier consists primarily of sterile water for injection (USP), glycerin (USP) and mannitol (USP). The thixotropic high yield strength gel is created by the Carbopol 974P NF (USP). Cytophil Tissue Marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location. There is no ferrous material used in the formulation of the Cytophil Tissue Marker. However, the safety and efficacy of the Ctyophil

Marker has not been established for Computer Tomography, Ultrasonography or Magnetic Resonance Imaging.

4.3 Substantial Equivalence

The following is the predicate device that is substantially equivalent to the Cytophil Tissue Marker:

K012955
Coaptite Tissue Marker and Coaptite FN Tissue Marker
BioForm Medical, Inc.
1875 South Grant St., Suite 110
San Mateo, CA 94402

The Cytophil Tissue Marker is substantially equivalent to BioForm's Coaptite Tissue Marker and Coaptite FN Tissue Marker which functions as a radiographic soft tissue marker.

4.4 Biocompatibility Evaluations

The battery of preclinical safety studies and animal implant studies show that the Cytophil Tissue Marker is biocompatible when injected into soft tissues.

4.5 Sterilization

Cytophil Tissue Marker is sterilized using steam. Processing is preformed by a contract sterilization company, Haemonetics, using a computer controlled autoclave system. Cycle parameters were validated using an overkill methodology to 10^{-6} SAL. Sterilization by the user is not required.

4.6 Pre-Clinical Tests Performed

In vivo and *in vitro* tests were performed to address irritation, sensitization, cytotoxicity, acute and sub-chronic toxicity, genotoxicity and hemolysis. Results identified the Cytophil Tissue Marker as a nonirritant, and nontoxic with no concerns for long-term safety.

4.7 Risk Assessment

The primary risks with Cytophil Tissue Marker have been identified through a risk assessment procedure in accordance with EN 1441.

4.8 Summary

The Cytophil Tissue Marker is safe and effective to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2008

Cytophil, Inc.
% Mr. Greg Johnson
President & CEO
5546 North Santa Monica Boulevard
White Fish Bay, Wisconsin 53217

Re: K072219
Trade/Device Name: Cytophil Tissue Marker and Cytophil Tissue Market SM
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: December 31, 2007
Received: December 31, 2007

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use/Intended Use Statement

510(k) Number: K072219

Device Name: Cytophil Tissue Marker and Cytophil Tissue Market SM

Indications for Use:

Cytophil Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X_____ *or* Over-the-Counter Use _____
(Per 21 CFR 801.109

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072219